

Patient Group Direction: For the supply of ASPIRIN 75MG DISPERSIBLE TABLETS by GPhC Registered Pharmacists & Pharmacy Technicians working in community pharmacies in Somerset to pregnant patients considered to be at high risk of pre-eclampsia (PGD MAS 7 Version 3.0)

Staff involved in the development of this PGD:

	Name	Signature	Date
Physician	Dr Andrew Tresidder NHS Somerset Medicines Programme Board Chair		26.11.2025
Pharmacist	Hels Bennett Medicines Manager, NHS Somerset ICB		26.11.2025

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Authorised for use across NHS Somerset ICB by:

Shelagh Meldrum, Chief Nursing Officer for NHS Somerset ICB (Acting as Clinical Governance Lead)

Signed:  Date: 26 Nov 2025

Valid from: 8 December 2025
Expiry Date: 7 December 2027

TO BE COMPLETED BY PHARMACY AUTHORISING MANAGER:

I,, as authorising manager for
..... pharmacy, have read and approved this PGD for use by
GPhC Registered Pharmacists and Pharmacy Technicians working at my pharmacy. I understand that I am responsible for ensuring that pharmacy staff have adequate training to ensure that ASPIRIN 75MG DISPERSIBLE TABLETS is supplied to patients in strict accordance with this PGD.

Signed..... **Dated**.....

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N.B. You must be authorised by name, under the current version of this PGD before you attempt to work in accordance with it.

1. Clinical Condition

Definition of condition/situation

- Pregnant patients considered to be at high risk of pre-eclampsia who are advised to take low dose aspirin as per [NICE guidelines \(NG133\)](#).

Criteria for inclusion

- Aged 16 years or over
- Valid informed consent given
- Pregnant patients at high risk of pre-eclampsia.
Patients at high risk are those with **any** of the following:
 - hypertensive disease during a previous pregnancy (pre-eclampsia or pregnancy induced hypertension)
 - chronic kidney disease
 - autoimmune disease such as systemic lupus erythematosus or antiphospholipid syndrome
 - type 1 or type 2 diabetes
 - chronic hypertension outside of pregnancy requiring antihypertensive treatment (as defined by [NICE](#))

Or: Pregnant patients with **two or more** moderate risk factors for pre-eclampsia.

Factors indicating moderate risk are:

- Nulliparity (never previously given birth)
- age 40 years or older
- pregnancy interval of more than 10 years
- body mass index (BMI) of 35kg/m² or more at first visit
- family history of pre-eclampsia
- multiple pregnancy

Off-label use

The use of aspirin is off-label for this indication. Its use is in accordance with [NICE guideline NG133 Hypertension in pregnancy: diagnosis and management](#). Patients should be made aware of this off-label use in order to give informed consent.

Exclusion criteria

- Consent not obtained (if capacity is a problem, refer to GP)
- Patients under 16 years old
- Known hypersensitivity to aspirin, salicylic acid compounds, NSAIDs or prostaglandin synthetase inhibitors or to any of the excipients – see SPC for full details (link in references).
- Asthma triggered by aspirin or NSAIDs
- Peptic ulceration or history of peptic ulceration and/or gastric/intestinal haemorrhage, or other kinds of bleeding e.g. cerebrovascular haemorrhages
- Known or suspected severe hepatic impairment
- Known or suspected severe renal impairment
- Active or history of gout
- Haemorrhagic diathesis; coagulation disorders such as haemophilia and thrombocytopenia.
- Patients with Glucose-6-phosphate dehydrogenase deficiency
- Patients taking potentially teratogenic, or teratogenic medications including those that are included in Pregnancy Prevention Programmes – **urgently refer to GP/specialist for review**

[Drug Safety Update - GOV.UK](#)

- Patients taking a medicine considered to be high risk in pregnancy – **urgently refer to GP/specialist for review.**

Check [SmPC](#) and refer to [UKTIS](#) to see if a medicine is considered high risk in pregnancy.

- Patients on medications that have clinically significant interactions with aspirin or increase bleeding risk, requiring medical review and where relevant, consideration of gastro-protection - **refer to GP/specialist for review**

All concurrent medications must be checked for interactions. A detailed list of drug interactions is available in the individual product SPC, which is available from the Electronic Medicines Compendium website www.medicines.org.uk and the online version of the BNF <https://bnf.nice.org.uk/>

Caution	<ul style="list-style-type: none"> • For a full list of special warnings, precautions for use & interactions consult the SmPC available at: https://www.medicines.org.uk/emc and the BNF • Current uncontrolled or severe asthma • Breastfeeding – Low dose aspirin passes into breast milk in negligible amounts. It can be used with caution during breastfeeding - refer to Specialist Pharmacy Service for further guidance: https://www.sps.nhs.uk/articles/using-antiplatelet-medicines-during-breastfeeding/ • Urgently refer to patient's GP / specialist if patient is taking a medicine / drug which requires urgent review in pregnancy. This includes any prescribed, OTC, or illicit drug the patient says they are taking which may need GP or specialist review in pregnancy. Check SmPC and refer to UKTIS to see if a medicine is considered high risk in pregnancy. • Note: Selective serotonin-reuptake inhibitors (SSRIs) should not usually be stopped because of pregnancy, however patients taking SSRIs should have an urgent review for consideration of GI protection due to an increased risk of bleeding when taking concurrently with aspirin.
Action if excluded	<ul style="list-style-type: none"> • Document reason for exclusion and any action taken or advice given in the clinical records. • Refer to appropriate medical practitioner or for urgent medical attention as appropriate to avoid delay in treatment. • Refer to medical practitioner if patient excluded or if no valid consent.
Action if patient refuses medication	<ul style="list-style-type: none"> • Refer to medical practitioner or for urgent medical attention as appropriate.

2. Characteristics of Staff

Professional qualification to be held by staff working under this Patient Group Direction

Pharmacists and pharmacy technicians currently registered with the General Pharmaceutical Council (GPhC)

Additional requirements

- The registered healthcare professional authorised to operate under this PGD must have undertaken appropriate education and training and declared themselves competent to undertake clinical assessment of patient leading to diagnosis of the condition(s) listed in this PGD.
- Must be familiar with NICE guidance 'Hypertension in pregnancy: diagnosis and management NICE guideline [NG133]: <https://www.nice.org.uk/guidance/ng133/chapter/Recommendations>
- Must be familiar with NICE guidance on PGDs and competent in the use of PGDs (see [NICE competency framework](#) for health professionals using PGDs). Suggested recommended training - [eLfh PGD elearning programme](#)
- Must have access to the PGD and associated online resources relating to the use of the PGD
- Must have access to current BNF (BNF online is recommended)
- Consultation room available for discussion
- CPPE level 2 Safeguarding children and vulnerable adults (including updates), or equivalent
- Must have completed initial training and/or be familiar with the current service level agreement.
- Individuals operating under this PGD must be assessed as competent or complete a self-declaration of competence to operate under this PGD
- Staff operating under this PGD should review their competency using the [NICE Competency Framework for health professionals using patient group directions](#)
- It is the responsibility of the individual to keep up-to-date with their continued professional development, in line with GPhC requirements
- The individual must be alert to changes in Summaries of Product Characteristics, and Drug Safety Updates from the MHRA.
- Individuals operating under this PGD are personally responsible for ensuring they remain up to date with the use of all medicines and guidance included in the PGD - if any training needs are identified these should be addressed and further training carried out as required.

The decision to supply any medication rests with the individual registered health professional. PGDs do not remove inherent professional obligations or accountability. It is the responsibility of each professional to practice only within the bounds of their own competence and in accordance with their own Code of Professional Conduct.

3. Description of Treatment

Name of Medicine	<ul style="list-style-type: none"> Aspirin 75mg dispersible tablets
Legal Class	<ul style="list-style-type: none"> POM (Prescription Only Medicine)
Storage	<ul style="list-style-type: none"> Do not store above 25°C Keep the product in the original container in order to protect from light and moisture
Method or route of administration	<ul style="list-style-type: none"> Oral
Dose to be used	<ul style="list-style-type: none"> 150mg (Two 75mg tablets)
Frequency	<ul style="list-style-type: none"> 150mg (Two 75mg tablets) ONCE daily at night, with or after food. To be taken from 12 weeks gestation until birth of the baby.
Total dose and number of times drug to be given. Details of supply (if supply made)	<ul style="list-style-type: none"> An initial supply of 112 tablets It is intended that the GP will continue to supply the medication thereafter However, further supplies of 28 days duration may be supplied against this PGD if required <p><u>Off-label use</u> The use of aspirin is off-label for this indication. Its use is in accordance with NICE guideline NG133 Hypertension in pregnancy: diagnosis and management. Patients should be made aware of this off-label use in order to give informed consent.</p>

Advice and information to patient/carer including follow-up

- Ensure that the Patient Information Leaflet (PIL) is provided and advise the patient to read the leaflet before using the medicine and that the pharmacy can be contacted if any queries arise.
- Provide patient with the leaflet '**Taking aspirin during pregnancy to reduce the risk of pre-eclampsia**', available from <https://nhssomerset.nhs.uk/prescribing-and-medicines-management/shared-care/>

Further information can be found here:

- [Pregnancy, breastfeeding and fertility while taking low-dose aspirin - NHS](#)
- <https://www.medicinesinpregnancy.org/leaflets-a-z/aspirin/>

- Provide full explanation of the risks and benefits to the patient (including the off-label use of the medicine in order to obtain informed consent).
- Advise patient that the tablet should be dispersed in water and taken with or after food - aspirin should not be taken on an empty stomach.
- Drinking alcohol with aspirin may increase the risk of gastrointestinal bleeding and prolong bleeding time. It is recommended not to drink alcohol at all while pregnant.
- No other NSAID or aspirin containing products including over the counter analgesic preparations should be taken
- Provide information on possible side-effects and management.

The following are well known side-effects of aspirin; see the Summary of Product Characteristics (SmPC) <http://www.medicines.org.uk/emc/> and the current edition of the [BNF](#) for full details and updates:

- indigestion, nausea, vomiting, diarrhoea and gastrointestinal bleeding which can lead to haemorrhage and perforation
 - bruising or bleeding more easily e.g. cuts may take longer than normal to stop
 - aspirin may precipitate bronchospasm and induce asthma attacks or other hypersensitivity reactions in susceptible individuals
- The patient should be advised to stop aspirin and seek emergency advice and assistance if they notice any of the following serious side effects:
 - Sudden wheezing, swelling of the lips, face or body, rash, fainting or difficulties swallowing (severe allergic reaction)
 - Reddening of the skin with blisters or peeling which may be associated with a high fever and joint pains. This could be erythema multiforme, Stevens-Johnson syndrome or Lyell's syndrome.
 - Unusual bleeding, such as coughing up blood, blood in vomit or urine, or black stools
 - Advise patient to discuss with their midwife, so they are aware that they have initiated or will initiate aspirin at 12 weeks.

- The individual should be advised to seek medical advice in the event of an adverse reaction or if they have any concerns.

Adverse effects: Any serious adverse reaction should be documented e.g. in the consent forms, patient's medical record and the GP should also be informed. Unusual /persistent side effects should be followed up with a medical practitioner.

Any **serious** adverse events that may be attributable to aspirin should be reported to the MHRA using the yellow card system (<https://yellowcard.mhra.gov.uk/>) and also follow the local incident reporting procedure.

Other considerations

Consider whether patient may also be eligible for treatment under *PGD MAS 8: For the supply of **FOLIC ACID 5mg TABLETS** by GPhC Registered Pharmacists & Pharmacy Technicians working in community pharmacies in Somerset to reduce the risk of neural tube defect or to compensate for the increased demand for folate during pregnancy.*

Specify method of recording supply /administration including audit trail

It is a legal requirement to keep auditable records of administration and supply of medication via a PGD.

All records should be clear, legible and contemporaneous.

All records should be kept in line with [national guidance](#). This includes individual data, master copies of the PGD and lists of authorised practitioners.

Information entered into a patient clinical record should include:

- Patient's name, address and date of birth
- Informed consent given
- Specify how the individual has/has not met the criteria of the PGD, including risk factors
- Name, strength, form and quantity of medication supplied
- Date of supply
- Information and advice given to the patient.
- Signature/name and GPhC number of pharmacist or pharmacy technician who supplied the medication, and name and address of pharmacy
- Details of any drug interactions experienced
- Details of any adverse reactions experienced
- Any patient decline or reason for exclusion
- Any referral arrangements
- Record that medicine supplied via Patient Group Direction
- Recording of any prescription charges / exemptions

- Consultation details to be recorded on PharmOutcomes (ideally at time of consultation but must be within 48 hours)

The GP practice should be informed of the consultation and supply of medication (this will be done automatically via PharmOutcomes).

A computer or manual record of all individuals receiving treatment under this Patient Group Direction should also be kept for audit purposes within each pharmacy. Check with employer which method of recording is to be used.

Data must be stored in accordance with Caldicott guidance and the Data Protection Act.

References used in the development of this PGD:

- PMP Aspirin National PGD template FINAL V2.0 October 2024
<https://www.sps.nhs.uk/articles/aspirin-tablets-for-use-within-antenatal-and-maternity-services/>
- Summary of Product Characteristics (SPC) www.medicines.org.uk
- Current edition of [BNF \(British National Formulary\) | NICE](#)
- General Pharmaceutical Council [standards](#)
- 'National Institute for Health and Care Excellence. Medicines Practice Guidelines, 'Patient Group Directions' Last updated March 2017.
<https://www.nice.org.uk/Guidance/MPG2>
- Hypertension in pregnancy: diagnosis and management NICE guideline [NG133] Published: 25 June 2019 Last updated: 17 April 2023
<https://www.nice.org.uk/guidance/ng133/chapter/Recommendations>
- Drugs & Lactation Database (LactMed) accessed 21.10.2025
<https://www.ncbi.nlm.nih.gov/books/NBK501196/>
- The Breastfeeding Network accessed 21.10.2025 [Low dose aspirin and breastfeeding – Breastfeeding and Medication \(breastfeeding-and-medication.co.uk\)](#)
- [USE OF ASPIRIN AND ASPIRIN OVERDOSE IN PREGNANCY – UKTIS](#)
- Specialist Pharmacy Service accessed 21.10.2025
<https://www.sps.nhs.uk/articles/using-antiplatelet-medicines-during-breastfeeding/>
- Shared decision making NICE guideline [NG197] 12.08.2021 [Overview | Shared decision making | Guidance | NICE](#)
- [Coronavirus \(COVID-19\), infection in pregnancy | RCOG](#) Version 16 Published December 2022

Please refer to the summary of product characteristics for full information

This Patient Group Direction is operational from 8th December 2025 and expires 7th December 2027

Version History

Version	Date	Brief Summary of Change	Owner's Name
0.1	09.08.2021	New PGD created	Hels Bennett, Medicines Manager, Somerset CCG
0.2	06.10.2021	Minor updates following comments from Somerset FT, LPC & LMC	Hels Bennett, Medicines Manager, Somerset CCG
1.0	01.12.2021	Minor updates following comments from Somerset CCG Prescribing & Medicines Management committee	Hels Bennett, Medicines Manager, Somerset CCG
1.1	08.12.2021	PGD updated with RCOG guidance: Coronavirus (COVID-19) infection in pregnancy. Current COVID-19 infection added to Exclusion Criteria, advice to patient added	Hels Bennett, Medicines Manager, Somerset CCG
2.0	18.10.2023	Reviewed against national aspirin PGD template published Feb 2022. Inclusion criteria updated from 17+ to 16+ years. 'First pregnancy' changed to 'nulliparity'. Reference to Folic acid PGD added. Current uncontrolled or severe asthma added as Caution. Minor updates & formatting changes. Approved at Somerset Medicines Programme Board October 2023.	Hels Bennett, Medicines Manager, NHS Somerset ICB
3.0	10.11.2025	PGD planned review. Updated to include supply by GPhC registered pharmacy technicians. Current COVID-19 infection removed as Exclusion & advice re: stopping aspirin during Covid-19 infection removed as per updated RCOG guidance. Coronavirus (COVID-19), infection in pregnancy RCOG Further information added to exclusion criteria section. List of medicines removed - all concurrent medicines to be checked for interactions / increased risk of bleeding with aspirin / risk in pregnancy. Links added. Further information added to Caution section including re: breastfeeding, SSRIs & links. Approved at Somerset Medicines Programme Board November 2025.	Hels Bennett, Medicines Manager, NHS Somerset ICB